

### **REMARKS**

Claims 1-22 are currently pending in the application. By this Amendment, claims 1, 5-7, 13, 14 and 17-22 are amended. In the Office Action, claims 1-22 were rejected. Claims 5 and 17 are objected to for certain informalities. Claims 5-7 and 13-15 are rejected under 35 USC § 112 (second paragraph) for failing to point out and distinctly claim the inventive subject matter. Claims 1, 2, 4-15 and 18-20 are rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 5,156,594 to Keith (hereafter "Keith"). Claims 3, 16 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Keith in view of U.S. Patent No. 6,309,379 to Willard (hereafter "Willard"). Claims 21 and 22 are rejected as being unpatentable over Keith in view of U.S. Patent No. 6,030,405 to Zarbatany (hereafter "Zarbatany"). Claim 1-18 are also rejected on the grounds of nonstatutory obviousness-type double patenting.

Reconsideration of the rejected claims is respectfully requested in view of the above amendments and following remarks.

#### **Priority Claim**

The present application is a division of prior application 09/311,498, filed May 13, 1999 (now U.S. Patent No. 6,635,029, issued October 21, 2003). By this Amendment, the specification has been revised to include reference to the prior application in the first sentence of the application. The reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence of the specification or an application data sheet. However, the information concerning the priority benefit was recognized by the Office as shown by its inclusion on the first filing receipt of the present application. Thus, a petition under 37 CFR 1.78(a) and the associated surcharges are not required.

#### **Claim Objections**

Claims 5 and 17 are objected to for containing typographical errors and/or improper antecedent basis. Claims 5 and 17 have been amended to resolve these deficiencies. Applicant respectfully submits the objections have now been overcome and request withdrawal of the objections.

Rejections under 35 USC § 112

Claims 5-7 and 13-15 are rejected for failing to point out and distinctly claim the inventive subject matter. Specifically, in claims 5 and 13, the phrase “said lateral opening of said guide tube” is deemed unclear, as the guide tube has not been established as having a lateral opening. Also, in claims 6 and 14, the term “said two tubes” is deemed unclear. Claims 5-7 and 13-14 have been amended to obviate these concerns. (Applicant’s representatives note claim 15 was included in this rejection under 35 USC § 112, but that no rationale for the rejection was provided. Applicant’s representatives have identified no basis for a rejection of claim 15 under 35 USC § 112.) Thus, Applicant respectfully request withdrawal of the rejection of claim 5-7 and 13-14 under 35 USC § 112.

Keith does not anticipate the claims

The Office Action rejects claims 1, 2, 4-15 and 18-20 as being anticipated by Keith. Keith discloses an over-the-wire balloon dilatation catheter that has a stainless steel hypotube catheter shaft, an intermediate sleeve section bonded to the shaft and a distal balloon section connected to the sleeve section.

To establish a prima facie case of anticipation under 35 U.S.C. § 102(b), the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. MPEP 2131. Applicant respectfully submits that this criterion has not been met for Keith as applied to claims 1, 2, 4-15 and 18-20 of the present invention, as amended.

For example, claim 1 of the present invention recites, in part, “A catheter structure comprising: a main tube having a proximal end and a distal end, said main tube distal end having a lateral aperture delimiting a main tube edge; a distal tube having a proximal end and a distal end, said proximal end *being slantwise cut* defining a distal tube outer edge; and a guide tube having a proximal end and a distal end, ... *said guide tube proximal end being flute cut defining a proximal guide tube edge....*” Keith fails to disclose either a slantwise cut for a distal tube nor a flute cut for the proximal end of the guide tube, as recited in claim 1. Furthermore, Keith fails to suggest the arrangement of claim 1, as the arrangement of components in Keith are neither adaptable to nor would they derive benefit from the features of claim 1. Applicant respectfully

submits these claimed feature are more than trivial, in that they allow for (at least) the robust structure and ease of assembly the invention provides. For at least this reason, Keith fails to teach or suggest all the elements of claim 1. Thus, Applicant respectfully submits that the rejection of claim 1 under 35 USC § 102(b) is now moot and that the claim is now in condition for allowance.

Claims 2, 4-15 and 19-20 depend directly or indirectly from claim 1 and incorporate all the limitations of claim 1. Thus, Applicant submits these dependent claims are allowable for at least the reasons cited above with respect to claim 1.

Similar to claim 1, claims 18 recites, in part, a side port assembly comprising a “distal tube having a ... distal proximal end being slantwise cut defining a distal tube outer edge” and a “guide tube proximal end being flute cut defining a proximal guide tube edge.” For the reasons recited above with respect to claim 1, Applicant respectfully submits that Keith also fails to teach or suggest all the elements of claim 18.

Applicant respectfully submits that claims 1, 2, 4-15 and 18-20 are now in condition for allowance.

Keith and Willard do not render the claims obvious

Claims 3, 16 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Keith in view of Willard. Willard discloses an intravascular selection sheath that comprises a tubular body having proximal, intermediate and distal sections and a lumen extending therethrough. The portion of the lumen in the distal section can be occupied by only one of the other intravascular devices of the predetermined sizes at a given time.

To establish a prima facie case of obviousness, three criteria must be met. First, there must be some reason to modify the reference or to combine the reference teachings. Second, there must be some expectation of success. Third, the prior art references must disclose or suggest all of the claimed features. See MPEP 2143 and the May 3, 2007 letter from the PTO Deputy Commissioner for Patent Operations regarding *KSR Int'l Co. v. Teleflex, Inc.* Applicant respectfully submits that these criteria have not been met for Keith in view of Willard as applied to claims 3, 16 and 17 of the present invention.

Claims 3, 16 and 17 depend directly or indirectly from claim 1 and incorporate all the limitations of the base claims. As noted above with respect to claim 1, Keith fails to teach or suggest at least the claimed distal tube proximal end being slantwise cut and a guide tube proximal end being flute cut. Willard fails to supply this deficiency, since the disclosure of Willard does not include any structure with a slantwise cut or a flute cut, nor does Willard disclose use of a structure that would benefit from such configurations. Thus, Applicant submits that a prima facie case of obviousness is lacking for claim 3 for at least this reason and that the claim is now in condition for allowance. Withdrawal of the rejection of claims 3, 16 and 17 based on 35 USC § 103(b) is requested.

Keith and Zarbatany do not render the claims obvious

Claims 21 and 22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kieth in view of Zarbatany. Zarbatany discloses a dilation catheter having a balloon inflation shaft with an inflation lumen into which a stiffening wire extends and a guidewire shaft having a guide wire lumen adjacent to the balloon. The stiffening wire includes at least two stepped diameter reductions along its length to vary stiffness from a stiff proximal end providing improved pushability to a less stiff distal end providing improved trackability.

Applicant respectfully submits that the criteria to establish a prima facie case of obviousness have not been met for Keith in view of Zarbatany as applied to claims 21 and 22 of the present invention.

Claims 21 and 22 depend directly or indirectly from claim 1 and incorporate all the limitations of the base claims. As noted above with respect to claim 1, Keith fails to teach or suggest at least the claimed distal tube proximal end being slantwise cut and a guide tube proximal end being flute cut. Zarbatany fails to supply this deficiency, since Zarbatany also includes no structure that with a slantwise cut or a flute cut, or any structure that would benefit from such configurations. Thus, Applicant submits that a prima facie case of obviousness is lacking for claim 21 and 22 for at least this reason and that the claim is now in condition for allowance. Withdrawal of the rejection of claims 21 and 22 based on 35 USC § 103(b) is requested.

Double Patenting

Claim 1-18 are also rejected on the grounds of nonstatutory obviousness-type double patenting. Particularly claims 1-18 are rejected as being unpatentable over claims 1-15 of U.S. Patent No. 6,635,029.

Claim 1 has been amended to include features, such as at least the claimed distal tube proximal end being slantwise cut, that are not included in the claims of U.S. Patent No. 6,635,029. Claims 2-18 depend directly or indirectly from claim 1 and incorporate all the limitations of claim 1. Thus Applicant respectfully submit the claims, as amended, are not patentably indistinct from claims 1-15 of U.S. Patent No. 6,635,029. Withdrawal of the rejection is requested.

**CONCLUSION**

In view of the foregoing, the Applicant submits that this application is in condition for allowance and such disposition is earnestly solicited. If the Examiner believes that the prosecution of this case might be advanced by discussing the application with the Applicant's representative, in person, or over the telephone, we would welcome the opportunity to do so.

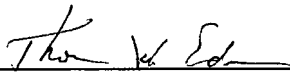
EXCEPT for fees payable under 37 CFR §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application, including fees due under 37 CFR §1.16 and 1.17 which may be required, including any required extension of time fees, or credit, any overpayment to deposit account No. 50-1349. This paragraph is intended to be a constructive petition for extension of time in accordance with 37 CFR §1.136(a)(3).

Respectfully submitted,

**HOGAN & HARTSON LLP**

Dated: September 10, 2007

**HOGAN & HARTSON LLP**  
555 13<sup>th</sup> Street, N.W.  
Washington, D.C. 20004  
(202) 637-5600 Tel.  
(202) 637-5910 Fax  
e-mail: [cjcrowson@hhlaw.com](mailto:cjcrowson@hhlaw.com)  
**Customer No. 24633**

By:   
Celine Jimenez Crowson  
Reg. No. 40,357  
  
Thomas W. Edman  
Reg. No. 51,643